UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: STRYKER LFIT V40 FEMORAL HEAD PRODUCTS LIABILITY LITIGATION	* * *	MDL No. 17-md-2768-IT
This Document Relates To:	* *	
Cooney v. Howmedica Osteonics Corp. et al., No. 17-cv-10829,	* * *	
Crowley v. Howmedica Osteonics Corp. et al., No. 17-cv-10830, and	* * *	
Mayo v. Howmedica Osteonics Corp. et al., No. 17-cv-10832.	* *	

MEMORANDUM AND ORDER

August 31, 2017

TALWANI, D.J.

I. Introduction

Defendants Howmedica Osteonics Corp. and Stryker Corp. (together, the "Howmedica Defendants") removed three Massachusetts state court actions to this court, asserting diversity of citizenship between them and Plaintiffs, and alleging that the non-diverse Defendant, Surgi-Care, Inc., was fraudulently joined. Notice of Removal, Cooney v. Howmedica Osteonics Corp. et al., 17-cv-10829 [#1]; Notice of Removal, Crowley v. Howmedica Osteonics Corp. et al., 17-cv-10830 [#1]; Notice of Removal, Mayo v. Howmedica Osteonics Corp. et al., 17-cv-10832 [#1]. The actions were related to the pending multi-district litigation, In re: Stryker LFIT V40 Femoral Head Products Liability Litigation, MDL No. 17-md-2768. Plaintiffs moved to remand these cases. See Mot. to Remand [17-md-2768, #148; 17-cv-10829, #11] (Cooney); Mot. to Remand [17-md-2768, #149; 17-cv-10832, #11] (Mayo); Mot. to Remand [17-md-2768, #150; 17-cv-

10830, #11] (Crowley). The Howmedica Defendants have opposed the motion.[1] For the reasons that follow, Plaintiffs' motions to remand are GRANTED.

II. Legal Standard

In general, "any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed" by the defendant to federal court. 28 U.S.C. § 1441. The court has original, diversity jurisdiction over actions when the amount in controversy is greater than $75,000 and there is complete diversity among the parties. 28 U.S.C. § 1332; Owen Equip. & Erection Co. v. Kroger, 437 U.S. 365, 373 (1978). It is the defendant's burden to show that federal jurisdiction lies. Hertz Corp. v. Friend, 559 U.S. 77, 96 (2010); Coll. of Dental Surgeons of Puerto Rico v. Connecticut Gen. Life Ins. Co., 585 F.3d 33, 39 (1st Cir. 2009). However, "[a] plaintiff may not thwart the exercise of a defendant's right of removal by fraudulently joining a non-diverse defendant who has no real connection to the case." In re Fresenius Granuflo/Naturalyte Dialysate Prods. Liability Litig., 76 F. Supp. 3d 321, 332 (D. Mass. 2015).

"[I]t is generally recognized that, under the doctrine of fraudulent joinder, removal is not defeated by the joinder of a non-diverse defendant where there is no reasonable possibility that the state's highest court would find that the complaint states a cause of action upon which relief may be granted against the non-diverse defendant." Universal Truck & Equip. Co., Inc. v. Southworth-Milton, Inc., 765 F.3d 103, 108 (1st Cir. 2014). Stated another way, "if the plaintiff fails to state a cause of action against a resident defendant, and the failure is obvious according to the settled rules of the state, the joinder of the resident defendant is fraudulent." Id. at 108 n.3

[1] Defendant Surgi-Care has filed no responses to the motions.

(quoting McCabe v. Gen. Foods Corp., 811 F.2d 1336, 1339 (9th Cir. 1987) (citing Moore's Fed.l Practice (1986) ¶ O.161[2])).

"In assessing a claim of fraudulent joinder, the court is not bound by the allegations in the complaint and may consider affidavits and other materials that bear on the question of whether there is a reasonable basis for joinder of a defendant." In re Fresenius Granuflo/Naturalyte Dialysate Prod. Liab. Litig., 76 F. Supp. 3d at 333. "[T]he court must resolve 'all disputed questions of fact and any ambiguities in the current controlling substantive law in plaintiffs' favor.'" Phillips v. Medtronic, Inc., 754 F. Supp. 2d 211, 215 (D. Mass. 2010) (quoting Badon v. RJR Nabsico Inc., 236 F.3d 282, 286 (5th Cir. 2000)).

III. Analysis

The Howmedica Defendants argue that Plaintiffs' claims against Defendant Surgi-Care are preempted by federal law. They also contend that Surgi-Care did not take title to the devices at issue, and therefore cannot be held liable under Plaintiffs' breach of warranty cause of action. The court considers whether Plaintiffs have failed to state a claim against Surgi-Care, and if so, that such failure is obvious.

A. Preemption

The doctrine of federal preemption is derived from the Supremacy Clause, which provides that federal law "shall be the supreme Law of the Land." U.S. Const., Art. VI, cl. 2; Arizona v. United States, 567 U.S. 387, 399 (2012). Preemption comes in several forms. Congress may include explicit statutory language signaling its intent to preempt state law. See Arizona, 567 U.S. at 399. The Howmedica Defendants do not dispute that there is no express federal preemption of actions involving medical devices cleared through a 510(k) process. Defs.' Opp'n to Pls.' Mot. to Remand ["Defs.' Opp'n"] 8 [17-md-2768, #167]; see also Riegel v.

Medtronic, Inc., 552 U.S. 312, 323 (2008); Medtronic, Inc. v. Lohr, 518 U.S. 470, 478-79, 497 (1996).

State law is also impliedly preempted in certain circumstances, including where state laws conflict with federal law. Arizona, 567 U.S. at 399-400; Mut. Pharm. Co., Inc. v. Bartlett, 133 S.Ct. 2466, 2473 (2013) ("Even in the absence of an express pre-emption provision, the Court has found state law to be impliedly pre-empted" under conflict preemption); Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 349 (2001) (finding implied preemption of state law fraud claims that conflicted with the FDA's regulatory scheme for 510(k)-cleared devices).

Implied preemption may include those instances when "'compliance with both federal and state regulations is a physical impossibility.'" Arizona, 567 U.S. at 399 (quoting Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963)); see also English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990) (finding implied conflict pre-emption where it is "impossible for a private party to comply with both state and federal requirements"). "The existence of a hypothetical or potential conflict is insufficient to warrant" preemption. Rice v. Norman Williams Co., 458 U.S. 654, 659 (1982).

In PLIVA v. Mensing, the Supreme Court found that the FDCA's requirements for generic drugs implicitly preempted state failure-to-warn claims where the generic drug maker could not change the warning labels. 564 U.S. 604, 618 (2011). The Howmedica Defendants argue that compliance with both Massachusetts laws and federal laws is similarly a physical impossibility with regard to medical device distributors. To assess this argument, the court reviews Surgi-Care's obligations under both state and federal law.

1. Duties Under Massachusetts State Law

In Massachusetts, distributors may be held liable for breach of warranty, under either a theory of defective design or a failure to warn. Haglund v. Philip Morris, Inc., 847 N.E.2d 315,

322 (Mass. 2006); Stevens v. Cmty. Health Care, Inc., No. ESCV200702080, 2011 WL 6379298 at *1 (Mass. Super. Ct. Oct. 5, 2011). With respect to defective design claims, distributors of a manufacturer's product are liable for injuries caused by defects in that product where the plaintiff, at the time of the injury, was "using the product in a manner that the defendant . . . distributor reasonably could have foreseen." Haglund, 847 N.E.2d at 322 (citing Allen v. Chance Mfg. Co., 494 N.E.2d 1324, 1326 (Mass. 1986)); see also Mitchell v. Stop & Shop Cos., Inc., 672 N.E.2d 544, 545 (Mass. App. Ct. 1996) (citing Mass. Gen. L. ch. 106 §§ 2-314 & 2-315). With respect to failure to warn claims, liability stems from the principle that manufacturers and distributors have "a duty to warn foreseeable users of dangers in the use of that product of which he knows or should have known." Mitchell v. Sky Climber, Inc., 487 N.E.2d 1374, 1376 (Mass. 1986). A failure to adhere to this duty thus gives rise to liability under breach of warranty.

2. Duties Under Federal Law

The Howmedica Defendants assert that Surgi-Care, as a distributor and not a manufacturer, is prohibited from altering the design, labeling, packaging, instructions for use, or warnings of the FDA-regulated medical devices. Defs.' Opp'n 7-8 [17-md-2768, #167]. In support of this argument, the Howmedica Defendants point to 21 C.F.R. § 807.81, a regulation which provides that:

> Each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria: . . . (3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification: (i) A change or modification in the device that could significantly affect the safety or effectiveness of the device . . . .

21 C.F.R. § 807.20(a), in turn, provides that a person required to register his establishment is:

> An owner or operator of an establishment . . . who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use . . . The registration and listing requirements shall pertain to any person who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use, including any person who: (1) Initiates or develops specifications for a device that is to be manufactured by a second party; (2) Sterilizes or otherwise makes a device for or on behalf of a specifications developer or any other person; (3) Repackages or relabels a device; [or] (4) Reprocesses a single use device that has previously been used on a patient . . . .

The regulation exempts distributors from registration requirements, but only where such person "does not manufacture, repackage, process, or relabel a device." Id. § 807.20(c). Contrary to the Howmedica Defendant's suggestion, on its plain language, this section does not appear to prohibit Surgi-Care from altering the labeling and packaging of FDA-regulated medical devices, but does require that Surgi-Care, like the Howmedica Defendants themselves, would need to register and submit premarket notification submission to the Food and Drug Administration, if it repackages or relabels the device.

The Howmedica Defendants also point to an August 1989 document entitled "Labeling – Regulatory Requirements for Medical Devices" to support their assertion. See Defs.' Opp'n 8 [17-md-2768, #167] (citing U.S. Food & Drug Admin., Labeling Regulatory Requirements for Medical Devices ["Labeling Guidance"], available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095308.pdf). In that guidance document, the FDA stated that "any changes to labeling must be formally reviewed and authorized before implementation." Labeling Guidance 22. Again, however, the document does not prohibit a distributor from changing labels. Instead, it places obligations on the distributor who changes the label. See e.g. id. at 5 ("If a packer, distributor, or seller intends a device for

uses other than those intended by the person from whom he received the device, these parties must furnish adequate labeling in accordance with the new intended use.").

Defendants point to two Massachusetts cases resolving the question of impossibility preemption as applied to generic drug distributors. Defs.' Opp'n 10-11 [17-md-2768, #167]. There, the courts reasoned that the distributor of generic drugs cannot change labeling or warnings, because the labels and warnings for generic drugs are required to match the labels and warnings the FDA approved for the brand-name version of the drug. Stevens, 2011 WL 6379298, at *1 (citing Mensing, 564 U.S. at 613-15); Gentile v. Biogen Idec, Inc., No. 11–3500, 2016 WL 4168942, at *11 (Mass. Super. Ct. July 28, 2016). Rather, generic drug manufacturers and distributors could only change the label or warnings to the extent the brand name drug label or warnings had changed, and had no power to initiate any other change of their own volition. Stevens, 2011 WL 6379298, at *1; Gentile, 2016 WL 4168942, at *11. Thus, it was impossible for generic drug manufacturers and distributors to comply with both federal and state law. Here, however, Defendants have not provided this court with the regulatory framework to reach the same conclusion about prohibitions on medical device distributors. Notably, they offer no Massachusetts cases reaching that conclusion. Thus, it is not obvious that impossibility preemption would apply to a medical device distributor. Instead, there appears to be a reasonable possibility that Plaintiffs' breach of warranty liability claim could survive Defendants' preemption argument, and therefore, this case should be remanded back to the state courts.

B. Alleged Requirement that Distributor Take Title to the Device

The Howmedica Defendants, relying on Mason v. General Motors Corp., 490 N.E.2d 437 (Mass. 1986), argue further that Surgi-Care did not take title to the devices at issue and therefore cannot be held liable under a breach of warranty cause of action. In Mason, the Supreme Judicial Court held that "a warranty of merchantability is implied in two situations: (1) when title to

goods passes for a price, and (2) when a contract is made for the future passing of title to goods for a price." Id. at 440. But the issue in Mason was not whether a particular defendant held title, but whether there was any sale (or lease) leading to a warranty. Id. The court concluded that the dealership (which did hold title to the car) was not liable for breach of warranty as to potential customers, who test drove the car but did not purchase or lease the car. Id.

That a supplier in the chain of distribution may be liable regardless of whether it held title appears to correspond with the statutory langue, which describes potential defendants for such an action to include "the manufacturer, seller, lessor or supplier of goods . . ." Mass. Gen. L. ch. 106, § 2-318. The case law also supports Plaintiffs' broader reading of Massachusetts law. As the Massachusetts Court of Appeals explained:

> modern products liability law, . . . not only makes a manufacturer strictly liable, generally, for injuries caused by defects in its product, see Swartz v. General Motors Corp., 375 Mass. 628, 630, 378 N.E.2d 61 (1978); Back v. Wickes Corp., 375 Mass. 633, 639-641, 378 N.E.2d 964 (1978); Mason v. General Motors Corp., 397 Mass. 183, 187-191, 490 N.E.2d 437 (1986) (limiting strict liability to sales and leases), but extends strict liability as well to the distributor or retailer of the manufacturer's product. See G.L. c. 106, §§ 2-314 & 2-315; Collins v. Sears, Roebuck & Co., 31 Mass. App. Ct. 961, 961-962, 583 N.E.2d 873 (1992). The retailer or distributor who has acted merely as a conduit for the product and has not altered it or otherwise acted in a manner that contributed to the injuries may then normally sue the manufacturer of the defective product for indemnification. Wolfe v. Ford Motor Co., 386 Mass. 95, 100-101, 434 N.E.2d 1008 (1982). See also Oates v. Diamond Shamrock Corp., 23 Mass. App. Ct. 446, 448, 503 N.E.2d 58 (1987).

Stop & Shop Cos., Inc., 672 N.E.2d at 545. Accordingly, there appears to be a reasonable possibility that Massachusetts courts would find that Plaintiffs' breach of warranty liability claim against Surgi-Care would survive, even if Surgi-Care established that it was only a conduit and did not hold title to the devices.

IV. Conclusion

For the foregoing reasons, Plaintiffs' Motion to Remand [17-md-2768, #148; 17-cv-10829, #11], Motion to Remand [17-md-2768, #149; 17-cv-10832, #11], and Motion to Remand [17-md-2768, #150; 17-cv-10830, #11] are GRANTED.

IT IS SO ORDERED.

Date: August 31, 2017

/s/ Indira Talwani
United States District Judge